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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Comple	Complete if Known				
Application Number	10/702,210				
Filing Date	11/05/2003				
First Named Inventor	Yoseph Yaacobi				
Art Unit	1615				
Examiner Name	C. Azpuru				
Attorney Docket Number	2101 F US				

			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
(4X)	A1	^{US-} 6,120,460	09/19/2000	Abreu	
	A2	^{US-} 6,713,081	03/30/2004	Robinson et al.	
	/A3	^{US-} 2004/0180075	09/16/2004	Robinson et al.	
W	A4	^{US-} 2004/0219181	11/04/2004	Viscasillas	
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		FOREIC	SN PATENT DOCU	MENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
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Complete if Known Substitute for form 1449/PTO **Application Number** 10/702,210 Filing Date 11/05/2003 INFORMATION DISCLOSURE First Named Inventor Yoseph Yaacobi STATEMENT BY APPLICANT Art Unit 65 .(Usg.as many.sheets as necessary) ... Examiner Name 2101 F US Attorney Docket Number

Examiner	Cite		U. S. PATENT	OCUMENTS Name of Patentee or		
Initiats* No.1		Document Number Number-Kind Code ^{2 (F known)}	MM-DD-YYYY		Pages, Columns, Lines, When Relevant Passages or Relevant	
12	A1		404744000		Figures Appear	
(14.)		3,416,530	12/17/1968	R. A. Ness		
	A2	us- 3,828,777	08/13/1974	R. A. Ness		
	A3	^{US-} 4,014,335	03/29/1977	Arnold		
	A4	us- 4,300,557	11/17/1981	Refojo et al.		
	A5	us. 4,327,725	05/04/1982	Cortese et al.		
	A6	us- 4,853,224	08/01/1989	Wong		
	A7	us- 4,946,450	08/07/1990	Erwin		
_	A8	us- 4,997,652	03/05/1991	Wong		
	A9	us- 5,147,647	09/15/1992	Darougar		
	A10	^{US-} 5,164,188	11/17/1992	Wong		
	A11	^{US-} 5,178,635	01/12/1993	Gwon et al.		
	A12	US- 5,300,114	04/05/1994	Gwon et al.		
	A13	^{US-} 5,322,691	06/21/1994	Darougar et al.		
	A14	us- 5,378,475	01/03/1995	Smith et al.		
	A15	us 5,403,901	04/04/1995	Namdaran et al.		
	A16	us- 5,443,505	08/22/1995	Wong et al.		
	A17	US- 5,466,233	11/14/1995	Weiner et al.		
2	A18	^{US-} 5,466,466	11/14/1995	Muller		
/ W T	A19	us- 5,476,511	12/19/1995	Gwon et al		

Examiner	1	FORE	IGN PATENT DOCU	MENTS		
Initials*	Cite Foreign Patent Document	Publication Date	Name of Palentee or	Pages, Columns, Lines,	T	
/]		Country Code ³ Number ⁴ Kind Code ⁸ (# known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear	7
(NX)	A20	EP 0 904 787	03/31/1999	Santen Pharm Co		\vdash
	A21	DE 40 22 553	01/23/1992	H. Hund		
	A22	RU 2149615	05/27/2000	Nesterov		ř
	A23	WO 94/05257	03/17/1994	Allergan, Inc.		H
d	A24	WO 95/26734	10/12/1995	Freeman		\vdash
	A25	/) WO 95/28984	11/02/1995	Esscalon Ophtha		┢

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known						
Application Number	10/702,210					
Filing Date	11/05/2003					
First Named Inventor	Yoseph Yaacobi					
Art Unit	1615					
Examiner Name	Carlos Azpuru					
Attorney Docket Number	2101 F US \					

			U. S. PATENT		
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (7 troping}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Unes, Where Relevant Passages or Relevan Figures Appear
CAP	B1	^{US-} 5,516,522	05/14/1996	Peyman et al.	
	B2	^{US-} 5,632,984	05/27/1997	Wong et al.	
\neg	B3	^{US-} 5,679,666	10/21/1997	Clark	
	B4	^{US-} 5,710,165	01/20/1998	Kapin et al.	
	B5	US- 5,725,493	03/10/1998	Avery et al.	·
	В6	^{US-} 5,743,274	04/28/1998	Peyman	
	B7	us- 5,766,242	06/16/1998	Wong et al.	
	B8	^{US-} 5,766,619	06/16/1998	Aiache et al.	
	B9	^{US-} 5,770,592	06/23/1998	Clark	
	B10	^{US-} 5,773,019	06/30/1998	Ashton et al.	
	B11	^{US-} 5,797,898	08/25/1998	Santini, Jr. et al.	
	B12	^{US-} 5,824,072	10/20/1998	Wong	t
	B13	^{US-} 5,824,073	10/20/1998	Peyman	
	B14	^{US-} 5,830,173	11/03/1998	Avery et al.	
	B15	us- 5,836,935	11/17/1998	Ashton et al.	
	B16	us- 5,902,598	05/11/1999	Chen et al.	1
	B17	^{US-} 5,904,144	05/18/1999	Hammang et al.	
	B18	^{US-} 5,916,584	06/29/1999	O'Donoghue	
JAN	B19	us- 6,001,386	12/14/1999	Ashton et al.	

		FOREIG	N PATENT DOCU	MENTS		$\overline{}$
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	Ŀ	Country Code ³ Number ⁴ 'Kind Code ⁵ (# known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ*
OF	B20	WO 96/36377	11/21/1996	Optonol Ltd.		
	B21	WO 97/14415	04/24/1997	F. H. Faulding		
	B22	WO 98/23228	06/04/1998	Alza Corp.		
	B23	WO 98/43611	10/08/1998	Alza Corp.	·	
	B24	WO 99/07418	02/18/1999	Allergan Sales		
all	B25	WO 99/11244	03/11/1999	Control Del Sys		

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Substitute for form 1449/PTO		Comp	Complete If Known			
				Application Number	10/702,210	
INEC	PMATIO	N DISC	COSTIDE	Filing Date	11/05/2003	
	INFORMATION DISCLOSURE		First Named Inventor	Yoseph Yaacobi		
STATEMENT BY APPLICANT		Art Unil	1615			
(Use as many sheets as nocessary)				Examiner Name	Carlos Azaucu	
neet	3	of _	4	Attorney Docket Number	2101 F US 1	

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Examiner Initials*	Cite No.1	N	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
A	C1	US-	6,074,661	06/13/2000	Olejnik et al.	
	C2	US-	6,110,485	08/29/2000	Olejnik	
	C3	UŞ-	6,126,687	10/03/2000	Peyman	
	C4	us-	6,146,366	11/14/2000	Schachar	
	C5	US-	6,217,895	04/17/2001	Guo et al.	
	C6	US-	6,375,972	04/23/02	Guo et al.	
	C7	US-	6,378,526	04/30/2002	Bowman et al.	
	C8	US-	6,397,849	06/04/2002	Bowman et al.	
	C9	US-	6,413,245	07/02/2002	Yaacobi et al.	
	C10	US-	6,413,540	07/02/2002	Yaacobi	
	C11	US-	6,416,777	07/09/2002	Yaacobi	
.,	C12	US-	6,669,950	12/30/03	Yaacobi	
	C13	US-	4,624,848	11/25/1986	Lee	
	C14	US-	2002/188,282	12/12/02	Greenberg	
M	C15	US-	2003/175,324	09/18/2003	Robinson et al.	1
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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Т
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OPP	C20	WO 99/32104	07/01/1999	Alcon Labs .		_
	C21	WO 99/45920	09/16/1999	Johns Hopkins		
	C22	WO 00/37066	06/29/2000	Johns Hopkins		Г
	C23	WO 00/56340	03/22/2000	Control Del Sys	1	┢
	C24	WO 01/49226	07/12/2001	Univ of Sydney		Т
alt	C25	WO 02/100318	02/19/2002	Johns Hopkins		_

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INFO	RMATIO	N DISC	LOSURE	Filing Date	11/05/2003		
STA	TEMENT	BY AP	PLICANT	First Named Inventor	Yoseph Yaacobi		
	##			Art Unit	1615		
•	. (Use as many sheets as necessary)			Examiner Name	Carlos Aziewa		
Sheet	4	of	4	Attorney Docket Number	2101 F US		

		NON PATENT LITERATURE DOCUMENTS				
Examiner Cite No.1		Include name of the author (in CAPITAL LETTERS), tille of the article (when appropriate), tille of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
CAS	D1	*Bausch & Lomb and Control Delivery Systems Agree to Develop Breakthrough Therapeutic Products for Severe Eye Diseases; Business Wire via Firstl; NewsEdge Corp.; 06/15/1999; 4 pp				
	D2	"Method of Placing Imgation System into Tenon's Space," E.I. SIDORENKO, et al., Abstract of Russian Patent No. RU 2123314, issued 12/20/1998, 1 pg.				
	D3	"A New method for Posterior Sub-Tenon's Drug Administration," NESTEROV, et al., Ophthalmic Surgery, Vol. 24, No. 1, January 1993, pp. 59-61				
1	D4	DIALOG File 266:FEDRIP database record; Identifying No. 122098; "Implantation of a Sub-Tenon Drug Delivery Device Loaded with a Test Article in Rabbits and Distribution of the Test Article in Ocular Tissues;" Compiled and distributed by NTIS; 1 page; 06/03/1999				
	D5	DIALOG File 266: FEDRIP database record; Identifying No. 134284; "Implantation of a Sub-Tenon Drug Delivery Device Loaded with a Test Article in Rabbits and Distribution of the Test Article in Ocular Tissues;" Complied and distributed by NTIS; 1 page	1			
W	D6	DIALOG File 266: FEDRIP database record; Identifying No. 131478; "Ocular Bicavailability of AL-3789 and AL-4940 after Sub-Tenon's Injection of AL-3789 Ophthalmic Suspensions in New Zealand White Rabbits; Complied and distributed by NTIS; 1 page				
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1 Applicant's unique citation designation number (epitional). 2/Applicant is to place a check mark here if English tanguage Translation is attached.

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Application Number	10/702,210			
Filing Date	11/05/03			
First Named Inventor	YAACOBI			
Art Unit	1615			
Examiner Name	Carla Azoucu			
Attorney Docket Number	3 4			

	U.S. PATENT DOCUMENTS						
Examiner Initials		Document Number Number - Kind Code ² (<i>Il knowr</i>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
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<i></i>	<u>A2</u>	US-					
	A3	US-					
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Examiner Initials		Foreign Patent Document County Code3 -Number4 - Kind Code4 (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	76
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	A29					
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